7. 510(k) SUMMARY

NOV 17 2005

Contact Information

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Date Prepared July 12, 2005

Product and Trade Name *GIARDIA/CRYPTOSPORIDIUM CHEK™*

Classification

Giardia spp.
21 CFR 866.3220 Product Code: MHI

Cryptosporidium spp.
21 CFR 866.3220 Product Code: MHJ

Predicate Devices

ProSpecT® *Giardia/Cryptosporidium* Microplate Assay
Remel (Lenexa, KS – formerly Alexon Biomedical, Inc.)
K955157

Merifluor™ *Cryptosporidium / Giardia* Kit
Meridian Diagnostics (Cincinnati, Ohio)
K912408

Intended Use

The *GIARDIA/CRYPTOSPORIDIUM CHEK™* test is an enzyme immunoassay for the qualitative detection of *Giardia* cyst and *Cryptosporidium* oocyst antigen in human fecal specimens. It is indicated for use as an aid in the diagnosis of patients with diarrhea suspected of *Giardia* and/or *Cryptosporidium* gastrointestinal infections.

Device Description

The *GIARDIA/CRYPTOSPORIDIUM CHEK™* test uses monoclonal and polyclonal antibodies to cell-surface antigens of *Giardia* and an oocyst antigen of *Cryptosporidium*. The *Microassay Plate* in the kit contains immobilized monoclonal antibodies against the antigens and the *Conjugate* consists of polyclonal antibodies against the antigens. In the assay, an aliquot of a diluted fecal specimen is transferred to a microassay well. The immobilized monoclonal antibodies bind the *Giardia* and *Cryptosporidium* antigens if the antigens are present. Upon addition, *Conjugate* then binds to the antigen/antibody complex. Any unbound materials are removed during the washing steps. Following the addition of substrate, a color is detected due to the enzyme-antibody-antigen complexes that formed in the presence of *Giardia* or *Cryptosporidium* antigens and *Conjugate*.

7.1 Comparative Information of Equivalent Devices

Kit Name	510(k) Numbers	Intended Use	Format	Materials	Target Population
GIARDIA/ CRYPTOSPORIDIUM CHEK™	Subject to this 510(k)	Detection of *Giardia* cyst and *Cryptosporidium* oocyst antigen in fecal specimens	ELISA	Highly specific antibodies against *Giardia* and *Cryptosporidium*	Persons suspected of having *Giardia* or *Cryptosporidium* infection
Microscopy	N/A	Direct detection of *Giardia* cysts and *Cryptosporidium* oocysts in fecal specimens	Microscopy	Various Stains	Persons suspected of having *Giardia* or *Cryptosporidium* infection
ProSpecT® *Giardia/ Cryptosporidium* Microplate Assay	K955157	Detection of *Giardia* cyst and *Cryptosporidium* oocyst antigen in fecal specimens	ELISA	Highly specific antibodies against *Giardia* and *Cryptosporidium*	Persons suspected of having *Giardia* or *Cryptosporidium* infection
Merifluor™ *Cryptosporidium/ Giardia* Kit	K912408	Direct detection of *Giardia* cysts and *Cryptosporidium* oocysts in fecal specimens	DFA – Immuno-fluorescence	Highly specific antibodies against *Giardia* and *Cryptosporidium*	Persons suspected of having *Giardia* or *Cryptosporidium* infection

7.2 Summary of Performance Data

7.2.1 Summary of Clinical Evaluations

Tables 1 and 2 display the comparison of the *GIARDIA/CRYPTOSPORIDIUM CHEK™* test to a commercially available ELISA and to microscopy. Results are compiled from the three clinical study sites and include all samples used in the clinical evaluation of the test.

Table 1 displays the comparison of the *GIARDIA/CRYPTOSPORIDIUM CHEK™* test to a commercially available ELISA and to microscopy from all three test sites. The results show that, compared to a commercially available ELISA, the *GIARDIA/CRYPTOSPORIDIUM CHEK™* test exhibited 98.6% agreement for positive specimens, 98.7% agreement for negative specimens, and 98.6% agreement overall.

Table 2 displays the comparison of the *GIARDIA/CRYPTOSPORIDIUM CHEK™* test to IFA-confirmed microscopy results from Site 1. The results show that, compared to microscopic analysis, the *GIARDIA/CRYPTOSPORIDIUM CHEK™* test exhibited 97.6% sensitivity, 100% specificity, and 98.6% correlation.

TABLE 1: SUMMARY OF ALL STUDIES *GIARDIA/CRYPTOSPORIDIUM CHEK™* **Comparison to a commercially available ELISA (n = 590)**		**ProSpecT® *Giardia/Cryptosporidium* Microplate Assay**		
		Positive	Negative	Total
***GIARDIA/CRYPTOSPORIDIUM CHEK™* TECHLAB®, Inc.**	Positive	283	4	287
	Negative	4	299	303
	Total	287	303	590

***GIARDIA/CRYPTOSPORIDIUM CHEK™* vs. ProSpecT® *Giardia/Cryptosporidium* Microplate Assay**	**Percent Agreement**	**95% Confidence Interval**
Percent Agreement – Positive Specimens	98.6%	96.2% - 99.6%
Percent Agreement – Negative Specimens	98.7%	96.4% - 99.6%
Percent Agreement - Overall	98.6%	98.4% - 98.8%

TABLE 2: SUMMARY OF ALL STUDIES *GIARDIA/CRYPTOSPORIDIUM CHEK™* **Comparison to Microscopy** (*n* = 217)		Microscopy		
		Positive	Negative	Total
GIARDIA/CRYPTOSPORIDIUM CHEK™	Positive	121	0	121
	Negative	3	93	96
	Total	124	93	217

GIARDIA/CRYPTOSPORIDIUM CHEK™ vs. Microscopy	Result	95% Confidence Interval
Sensitivity	97.6%	92.6% - 99.4%
Specificity	100%	95.1% - 100%
Predictive Positive Value	100%	96.2% - 100%
Predictive Negative Value	96.9%	90.5% - 99.2%
Correlation	98.6%	98.2% - 98.9%

7.2.2 Reproducibility

Multi-site proficiency testing was conducted to establish the ability of the *GIARDIA/CRYPTOSPORIDIUM CHEK™* test to provide reproducible results in laboratory settings. A fecal panel was assembled and tested at TECHLAB®, Inc. Identical aliquots of the panel were tested at TECHLAB®, Inc. and two independent laboratories using the *GIARDIA/CRYPTOSPORIDIUM CHEK™* test. The fecal panel consisted of 24 samples: eight *Giardia*-positive samples, eight *Cryptosporidium*-positive samples, and eight samples negative for both parasites. Samples were selected that provided a range of absorbance values over the working range of the *GIARDIA/CRYPTOSPORIDIUM CHEK™* test (OD_{450} reading 0.0 – 4.0), including positive samples close to the positive/negative cut-off absorbance (OD_{450} 0.150). Each sample was tested during three independent trials over a three-day period. Proficiency testing demonstrated 100% correlation for all samples from all three testing sites.

7.2.3 Sensitivity

Sensitivity to each antigen preparation was evaluated in 6 separate trials, using three different lots of the *GIARDIA/CRYPTOSPORIDIUM CHEK™* test. The *GIARDIA/CRYPTOSPORIDIUM CHEK™* test was consistently positive at 375 *Giardia* cysts/mL, 0.8 ng recombinant cyst wall protein/mL, and 6250 *Cryptosporidium* oocysts/mL.

7.2.4 Specificity

Crossreactivity

An independent diagnostics laboratory evaluated the *GIARDIA/CRYPTOSPORIDIUM CHEK™* test using fecal specimens found to be positive for a variety of intestinal pathogens. No cross reactivity was observed with fecal specimens that contained any of the pathogens listed below. The number of specimens tested with each organism is shown in parentheses.

Ascaris lumbricoides eggs (26)
Blastocystis hominis (31)
Chilomastix mesnili (2)
Cyclospora cayetanensis (1)
Dientamoeba fragilis (10)
Diphyllobothrium latum eggs (1)
Endolimax nana (36)
Entamoeba histolytica/dispar (9)
Entamoeba coli (17)
Entamoeba hartmanni (4)
Enterobius vermicularis eggs (6)
Hymenolepis nana eggs (4)
Iodamoeba bütschlii (4)
Strongyloides stercoralis larvae (2)
Taenia spp. eggs (2)
Trichuris trichiura eggs (20)

The *GIARDIA/CRYPTOSPORIDIUM CHEK™* test was evaluated for crossreactivity with the bacterial and viral strains listed below. None of the strains were shown to crossreact with the *GIARDIA/CRYPTOSPORIDIUM CHEK™* test.

Escherichia coli
Escherichia coli 0157H7
Yersinia enterocolitica
Aeromonas hydrophila
Shigella dysenteriae
Salmonella typhimurium
Campylobacter fetus
Vibrio parahaemolyticus
Staphylococcus aureus
Klebsiella pneumoniae
Clostridium bifermentans
Bacillus subtilis
Adenovirus type 1
Adenovirus type 3
Adenovirus type 40
Human coronavirus
Coxsackievirus B3
Coxsackievirus B5
Echovirus 11
Echovirus 22
Enterovirus type 68
Enterovirus type 70
Escherichia coli ETEC (enterotoxic)
Escherichia coli EPEC (enteropathogenic)
Escherichia coli EIEC (enteroinvasive)
Salmonella typhimurium
Shigella flexneri
Campylobacter coli
Clostridium difficile
Staphylococcus aureus (Cowan's)
Staphylococcus epidermidis
Enterococcus faecalis
Bacteroides fragilis
Bacillus cereus
Adenovirus type 2
Adenovirus type 5
Adenovirus type 41
Coxsackievirus B2
Coxsackievirus B4
Echovirus 9
Echovirus 18
Echovirus 33
Enterovirus type 69
Enterovirus type 71

Interfering Substances

The following substances had no effect on positive or negative test results analyzed at the concentrations indicated: mucin (3.5% w/v), human blood (40% w/v), Imodium® (5% w/v), Kaopectate® (5 mg/mL), Pepto-Bismol® (5% w/v), fecal fat (stearic acid - 40% w/v), Metronidazole (0.25% w/v), Vancomycin (0.25% w/v).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 17 2005

David M. Lyerly, Ph.D.
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Re: k051929
Trade/Device Name: GIARDIA/CRYTOSPORIDIUM CHECK™
Regulation Number: 21 CFR 866.3220
Regulation Name: Entamoeba Histolytica Serological Reagents
Regulatory Class: Class II
Product Code: MHJ
Dated: October 20, 2005
Received: October 25, 2005

Dear Dr. Lyerly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE

510(k) Number (if known): K 051929

Device Name: *GIARDIA/CRYPTOSPORIDIUM CHEK™*

Indications For Use:

The *GIARDIA/CRYPTOSPORIDIUM CHEK™* test is an enzyme immunoassay for the qualitative detection of *Giardia* cyst and *Cryptosporidium* oocyst antigen in human fecal specimens. It is indicated for use as an aid in the diagnosis of patients with diarrhea suspected of *Giardia* and/or *Cryptosporidium* gastrointestinal infections.

FOR *IN VITRO* DIAGNOSTIC USE.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K051929